SECTION I

INVESTIGATIVE REPORT

INVESTIGATIVE FILE
OFFICE OF PUBLIC PROTECTION

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
Board of Registration in Pharmacy
Investigative Report

In the Matters of:

1. **PHA-2011-0309 Royal Palm Specialty Pharmacy (DS89765; Issued 04/29/11)**
2. **PHA-2012-0004 Karen A. Blakely (PH21868; Issued 10/08/92)**
3. **PHA-2012-0005 Mark J. Rubin (PH 233459; Issued 04/20/11)**
4. **PHA-2012-0006 Agnes S. Rubin (PH25022; Issued 04/20/01)**
5. **PHA-2012-0060 Joanne Blain (PT315; Issued 09/05/02)**
6. **PHA-2012-0061 Angel Figueroa (PT13937; Issued 05/05/11)**
7. **PHA-2012-0065 Gina M. Franconeri (PT1568; Issued 12/12/02)**

Current Manger of Record (MOR): **08/10/2011-present**
Karen A. Blakely (PH21868; Issued 10/08/92)
(Formerly Karen Blackmar and Karen Chesanek)

Former Manger of Record (05/25/11-08/10/11) and Current 100% President /Owner:
Agnes S. Rubin (PH25022; Issued 04/20/01)
(Formerly Agnes Bergeron and Agnes Kokosinski)

Investigator: Cheryl Lathum, PharmD, BCPS, RPh

Supervisor: Samuel J. Penta, RPh

Inspection December 21, 2011:

1. Samuel J. Penta, RPh, Supervisor of Investigations
2. Cheryl Lathum, PharmD, BCPS, RPh, Investigator

Inspection April 24, 2012:

1. Leo A. McKenna, PharmD, RPh, Quality Assurance Coordinator
2. William Frisch, RPh, Investigator
3. Cheryl Lathum, PharmD, BCPS, RPh, Investigator

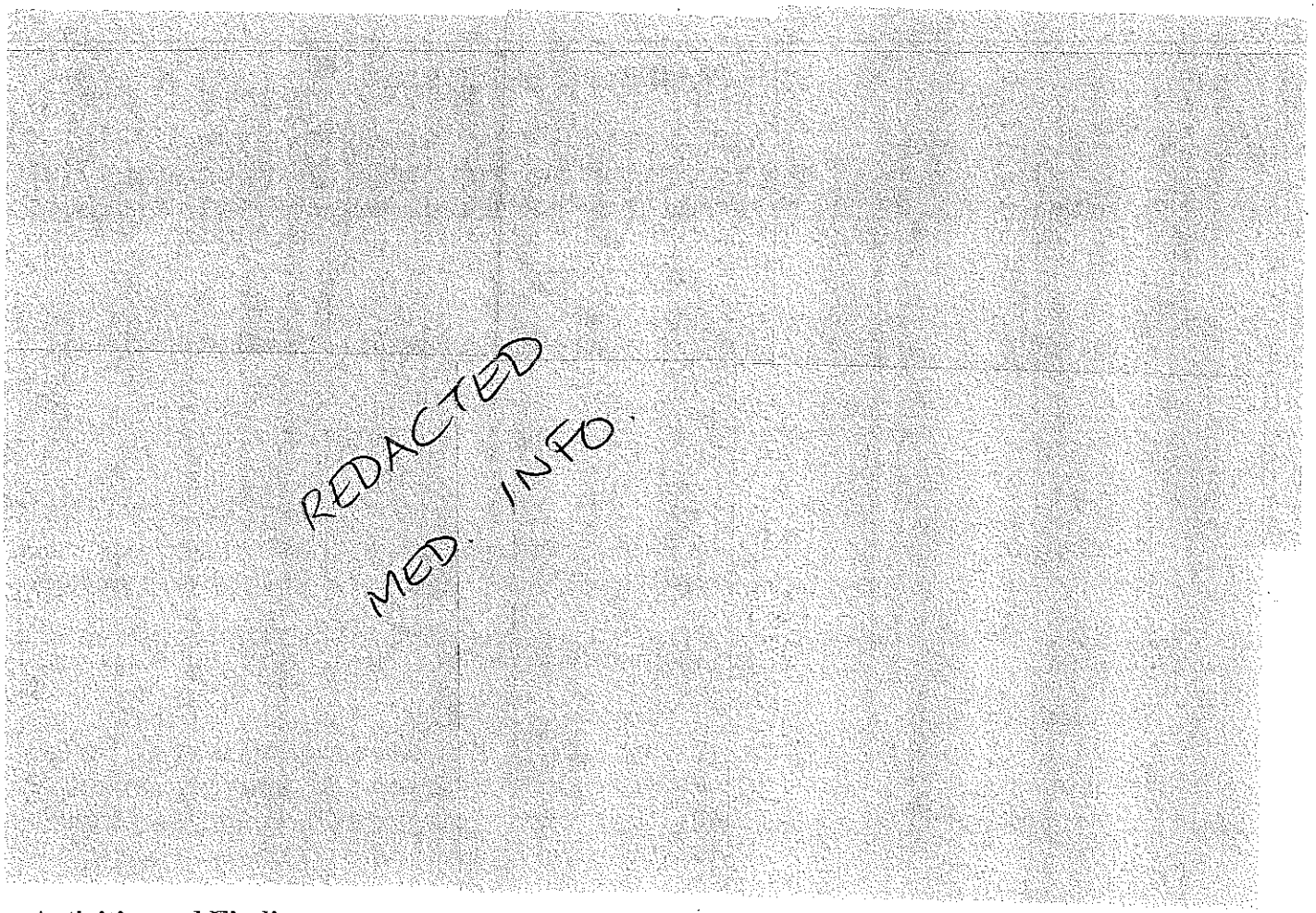
Allegation of Complaint: **give nature code and summarize the allegations:**

July 29, 2011:

The complainant [redacted] alleges that on July 29, 2011, Royal Palm Specialty Pharmacy (DS89765), located at 118 Main Street in Webster, Massachusetts failed to compound/verify/dispense a prescription properly. Specifically, a prescription for T3 10 mcg SR #30 capsules (Rx #213881) was compounded/verified/dispensed as T3 10 MG SR #30 capsules [redacted]

The complainant provided a certificate of analysis from Analytical Research Laboratories stating that the compounded capsules contained 10, 794.4 mcg/capsule and not the prescribed 10 mcg/capsule.

REDACTED:
MEDICAL INFO.



Activities and Findings:

Current MOR Karen Blakely (PH21868; Issued 10/08/92; no prior complaints) responds that Royal Palm Specialty Pharmacy (DS89765; Issued 04/29/11; no prior complaints) in Webster, Massachusetts compounded, verified and dispensed a prescription for T3 10 **mcg** with T3 10 **mg** (10,000 mcg).

Blakely commenced employment at Royal Palm Specialty Pharmacy on May 25, 2011 as a staff pharmacist. On August 10, 2011, Blakely became Manager of Record. Pharmacist Agnes Rubin was Manager of Record from May 25, 2011 to August 10, 2011. Agnes Rubin is the owner of Royal Palm Specialty Pharmacy, LLC in Webster, Massachusetts.

In written signed statement, current MOR Karen Blakely states, "The prescription was compounded July 29th according to a log made up by Mark Rubin (pharmacist) checked (incorrectly) by Karen Blakely. The product was labeled 10 mcg, but actually contained 10 mg per capsule. A trituration to dilute the active ingredient (T-3) should have been made when the powder arrived in the pharmacy. Pharmacist Karen did not realize the necessity of dilution-being that the actual strength is so minute that it is nearly impossible to measure on a scale. The actual log made would have been accurate to measure the diluted or triturated T3. The trituration would have made 1 mg weighed on the scale (of mixture) contain 1 mcg of active ingredient. Instead, 0.363gm of T-3 was weighed out to make 36 capsules, bringing the strength to 10 mg

per cap. The patient was given the completed prescription on Friday July 29th, 2011. [redacted] On Monday, Karen and Mark were discussing the Rx and realized the error. Karen called the patient [redacted] Karen told [redacted], that the med was incorrect and contained a much higher dose than prescribed. A short time later *[complainant]* called Karen to get the dose actually in the capsules, and was told 10 mg per capsule. In realization of this grave error, more training was done by Karen including Pharmacist's Letter programs (General Principles of Non-Sterile Compounding for Community Pharmacists, vol. 2009 course 14; and Keeping It Clean: Basics of sterile Compounding and USP Chapter <797> vol. 2010 course 314). She also signed on with PCCA (Professional Compounding Centers of America) for further training and as an immediate consultant resource. Mark Rubin and Karen Blakely cross check each other's calculations on every log. We regret that this error ever occurred, and are doing everything possible to prevent future mistakes."

MOR Blakely also completed Pharmacist's Letter Medication Safety: Strategies for Preventing Medication Errors (Volume 11, No 314).

MOR at time of incident Agnes S. Rubin (PH25022; Issued 04/20/01; no prior complaints) states that she was out on maternity leave during the time of this incident. In written signed statement she responds, "This incident occurred two weeks after I gave birth. I will refer and concur *(sic)* my answer to pharmacist Karen Blakely's statement…" An application for change of Manager of Record from Agnes Rubin to Karen Blakely was received by the Board of Registration in Pharmacy (Board) on August 15, 2011. The application was signed by current MOR Blakely and dated August 10, 2011.

Per 247 CMR 6.03 (1) (a), "Whenever there is a change in the pharmacist Manager of Record of a pharmacy or pharmacy department, an application for a change in pharmacist Manager of Record shall be obtained from and promptly submitted to the Board. A completed application shall be fully and properly completed and signed, under the penalties of perjury, by a duly authorized representative of the pharmacy or pharmacy department and include; a sworn statement confirming that a complete inventory of controlled substances in Schedules II, III, IV and V signed by the outgoing pharmacist Manager of Record and the incoming pharmacist Manager of Record has been taken and filed with the pharmacy's controlled substance records. In the event the outgoing pharmacist Manager of Record is unavailable due to death, serious illness, or termination for inappropriate handling of controlled substances, a staff pharmacist may be authorized to sign the inventory, provided the Board is notified at the time the application is submitted why the staff pharmacist is signing the inventory"

MOR Blakely provided a copy of the Schedule II inventory, signed by incoming MOR Blakely and outgoing MOR Agnes Rubin on August 10, 2011. No inventory of Schedule III- V was provided with both incoming MOR Blakely and outgoing MOR Rubin's signatures. MOR Blakely conducted an inventory of CII-V on November 17, 2011.

Pharmacist Rubin is listed as the pharmacist on the formula sheet. Pharmacist Rubin explains that he assisted in the formulation by remotely connecting via computer in order to get the formula into the software.

In a written, signed statement, pharmacist Mark J. Rubin (PH233459; Issued 04/20/11; no prior complaints) states, "I was not in the pharmacy at the time that this prescription was presented, nor have I have never *(sic)* seen the prescription that is in question. At that time, I was assisting pharmacist Karen Blakely using PK Software, For this particular log, I helped her with all the steps necessary in forming the log. For the reason of why such error occurred, I would have to refer you back to Karen's response..."

The prescription was entered correctly into the computer by certified technician Gina Franconeri (PT1568; Issued 12/12/02; no prior complaints). Technician Franconeri is no longer employed at Royal Palm Specialty Pharmacy.

The prescription was compounded by certified technician Joanne Blain (PT315; Issued 09/05/02; no prior complaints). In a written signed statement, technician Blain states, "I, Joanne Blain, being a compound technician, receive and make products that the pharmacist has created a log for. I do not know if log is correct according to the prescription, because I do not see those." Technician Blain continues, "On the morning of July 29, 2011, I was given a log for T3. I donned proper attire, cleaned the area, and verified lot numbers of ingredients. I then weighed out the ingredients as accurately as possible, with Angel Figueroa verifying my amounts. The final product was encapsulated, counted out and verified by the pharmacist and picked up by the customer later the same day."

In a written signed statement, technician Angel Figueroa (PT13937; Issued 05/05/11; no prior complaints) responds, "I, Angel Figueroa was called over to oversee the compound for *[patient]*. The log, for T-3 10mcg, was handed to Joanne Blaine on August 1st *(sic)* to fill. I signed off on the *(sic)* all the weights for the compound. The log was done by procedure from properly garbing up to weighing every drug out to the closest amount possible that was specified on log. Everything was weighed out signed off and then mixed until it was one uniform mixture. Once properly mixed, we then proceded *(sic)* to encapsulate the powder until all the medication was dispensed so that the prescription received was filled and verified then given to the customer."

Current MOR Blakely states, "The root cause analysis was due to a mathematical error. The outcome has prompted us to always put "trituration only" on the liothyronine bottle when it comes in. Also do a second check on calculations."

With compounding, there is no barcode scanning utilized or integrated into the compounding software. The policy at Royal Palm Specialty Pharmacy is to have one technician check each NDC of each ingredient as weighed, then have another technician check for accuracy.

On the day of incident, July 31, 2011 a total of 24 compounds were verified by MOR Karen Blakely between the hours of 10 AM – 6:30 PM. On August 1, 2011, a total of 9

prescriptions (4 compounds) were verified by MOR Karen Blakely between the hours of 10 AM – 6:30 PM.

Compound Training:

Blakely (on 7/5/11), Figueroa (on 6/29/11), and Blain (on 6/29/11) completed the following training in compounding:

1. General Principles of Non-Sterile Compounding for the Community Pharmacist
    a. Volume 2009 course #14; Self study #09014; Pharmacist Letter.
2. Non-Sterile Compounding for the Community Pharmacist; Topical Preparations and Oral Liquid Dosage Forms
    a. Volume 2009 course #15; Self-study #09015; Pharmacist Letter.
3. Keeping It Clean; Basics of sterile Compounding and USP Chapter <797>
    a. Volume 2010 course #314; Self study #100314; Pharmacist Letter.

Additionally, Blakely (on July 5, 2011), Blain (on June 29, 2011), and Figueroa (on June 29, 2011) completed Critical Point/Basic Compounding Skills Core Curriculum (10 continuing education hours). This consisted of the following 10 home study courses (1 continuing education hour each):

1. Quality and the Responsibilities of Compounding Personnel.
2. Cleaning and Disinfection of Pharmacy Controlled Environments.
3. Purpose and Effective Use of Policies and Procedures.
4. Documentation.
5. Non Hazardous Drugs- Personnel Cleansing and Garbing.
6. Employee Aseptic Technique Training and Competency Assessment.
7. Use of syringes, needles, vials, ampoules, and filters.
8. Labeling and packaging for delivery.
9. Quality release and final checks of CSPs.
10. Overview of Engineering Controls.

Pharmacist Mark Rubin completed the following training in compounding:

1. General Principles of Non-Sterile Compounding for the Community Pharmacist
    a. Volume 2009 course #14; Self study #09014; Pharmacist Letter (Completed 01/10/12).
2. Keeping It Clean; Basics of sterile Compounding and USP Chapter <797>
    a. Volume 2010 course #314; Self study #100314; Pharmacist Letter (Completed 01/10/12).
3. Critical Point/Basic Compounding Skills Core Curriculum (Completed 12/23/09).
4. Critical Point Environmental Sampling Series (Completed 03/24/10). This consisted of 4 home study courses (1 continuing education hour each):
    a. Environmental Sampling- The basics of Air Sampling.
    b. Environmental Sampling- Glove Fingertip Sampling.
    c. Environmental Sampling- Volumetric Air Sampling.
    d. Environmental Sampling- Surface Sampling.

5. Attending the Medical Educator Consortium's *Fellowship in Anti-Aging, Regenerative and Functional Medicine- Module IV* in Boca Raton, Florida on June 24-28, 2009. Twenty-four AMA PRA Category 1 credits were awarded.

Pharmacist and owner Agnes Rubin completed the following training in compounding:

1. General Principles of Non-Sterile Compounding for the Community Pharmacist
   a. Volume 2009 course #14; Self study #09014; Pharmacist Letter (Completed 01/24/12).
2. Keeping It Clean; Basics of sterile Compounding and USP Chapter <797>
   a. Volume 2010 course #314; Self study #100314; Pharmacist Letter (Completed 01/24/12).
3. Critical Point/Basic Compounding Skills Core Curriculum (Completed 01/06/10).
4. Critical Point Virtual Compounder Series (Completed 03/24/10). This consisted of 3 home study courses (1 continuing education hour each):
   a. The Virtual Compounder™ - Proper Personnel Cleansing and Garbing Procedures.
   b. The Virtual Compounder™ - Cleaning Solution Preparation.
   c. The Virtual Compounder™ - LAFW Cleaning.
5. Attending Educational Review Systems, Inc's *"Better Balance- Bio Identical Hormone Restoration"* on March 19-20, 2009. A total of 13.5 ACPE credits were awarded.
6. USP Chapter 795 Pharmaceutical Compounding- Nonsterile Preparations (Completed 11/12/08). One home study credit was awarded.
7. Attending the Medical Educator Consortium's *"Putting It All Together: The Nuts and Bolts of Hormone Restoration"* in Boca Raton, Florida on October 17, 2009. A total of 6.25 AMA PRA Category 1 credits were awarded.

As part of the plan of correction, additional training will be provided through PCCA's on-line tutorials, including aseptic hand washing, compounding techniques, aseptic gowning, geometric dilution, and filtration.

No Report of SRE:

Per 247 CMR 6.14, "Effective January 1, 2010, a pharmacy licensed by the Board is required to report to the Board any improper dispensing of a prescription drug that results in serious injury or death, as defined by the Board, as soon as is reasonably and practicably possible but not later than 15 business days after discovery or being informed of such improper dispensing." Current MOR Blakely responds, "The reason for not reporting the improper dispensing within a timely fashion was due to the fact that, I did not know if the results lead to serious injury. I tried to call [redacted] numerous times, but never received a phone call back. In doing my research for this medication, the adverse reactions are reversible. Until seeing the report from the Board of Pharmacy, I then realized what has transpired. So, immediately I reported the error."

No Report of Improper Drug Dispensing was received by the Board or Office of Public Protection (OPP).

Of note, the pharmacy's "Customer Complaint Log" and "Customer Complaint Record" (both signed by Karen Blakely and dated August 2, 2011) document that the error was discovered by the pharmacy on August 1, 2011 [redacted] Additionally, a letter dated August 15, 2011 was sent to Royal Palm Specialty Pharmacy by the patient's attorney. The letter advised Royal Palm Pharmacy that the error has caused [redacted]

April 24, 2012 Inspection (Follow-up to POC):

During an inspection on April 24, 2012, the plan-of-correction (POC) was reviewed with pharmacist Mark J. Rubin and Manager of Record Karen Blakely. The plan of correction stated that the pharmacy would promptly label the bulk liothyronine bottle with "trituration only" (i.e. to be diluted to a 1:1000 powder). In addition, all calculations would be checked by a second technician.

Investigator Lathum requested to observe the storage of the bulk liothyronine in the refrigerator. Investigator Lathum observed a bottle of liothyronine sodium 500 mg, not labeled as "trituration only", stored in close proximity to T3 (liothyronine) 1:1000 trituration and T-4 (levothyroxine) 1:1000 trituration.

Investigator Lathum observed that compounding technician Joanne Blain was checking her own calculations and not utilizing a second technician.

Investigator Lathum also observed liquid "HCG 6K" in the refrigerator, not labeled with a lot number or expiration date. Per 247 CMR 9.01(3), a pharmacist shall observe the standards of the current United States Pharmacopoeia.

Plan of Correction April 26, 2012:

On April 26, 2012, MOR Blakely conducted a meeting with pharmacy staff. During the meeting pharmacy staff was reminded, "Always get a second person to double check!" In addition, a "Checklist for Safety and Efficiency" was created and will be reviewed weekly by an assigned employee. This employee will report the outcome of the weekly check to a pharmacist. The check list includes verifying that "For Trituration Only" is clearly labeled on any bag /bin, containing any applicable medication (such as liothyronine sodium 500 mg). The checklist also includes confirming that all compound formula sheets have two visible signatures, attesting that all weights and measures have been done accurately.

Other Licenses:

Pharmacist Mark J. Rubin is a 1997 graduate of Long Island University's Arnold and Marie Schwartz College of Pharmacy and Health Sciences. In addition to Massachusetts, pharmacist Mark Rubin is also registered as a pharmacist in Arizona (S018091), Florida (PS32908), Oregon (RPH-0012180), Nebraska (13531), Georgia (RPH025721), Arkansas (PD11253), Tennessee (36342), and Louisiana (PST.019375). Pharmacist Mark J. Rubin has applied to be registered as a pharmacist in Kentucky (*NABP047562; Pending as of 05/01/12*).

Former MOR (and current owner of Royal Palm Specialty Pharmacy) Agnes Rubin is a 2001 graduate of the Massachusetts College of Pharmacy. In addition to Massachusetts, pharmacist Agnes Rubin is also registered as a pharmacist in Arizona (S017686), Nebraska (13074), Virginia (0202208745), Florida (PS38278), Oregon (RPH-0011596), Kentucky (014408), Louisiana (PST.018708), Tennessee (33388), Georgia (RPH025720), Arkansas (PD11225), Mississippi (12331), and Connecticut (PCT.0011826).

Current MOR Karen A. Blakely is a 1988 graduate of the University of Connecticut's School of Pharmacy. In addition to Massachusetts, pharmacist Karen A. Blakely is also registered as a pharmacist in Connecticut (PCT0007148).

Certified technician Joanne Blain is not registered in any other states.

In addition to Massachusetts, technician Angel Figueroa is registered as a pharmacy technician in Florida (RPT26666). Figueroa is not currently nationally certified.

In addition to Massachusetts (DS89765), Royal Palm Specialty Pharmacy, LLC is licensed in the following states:

State	Number
Alabama	113827
Alaska	1080
Arizona	Y005385
Arkansas	OS02310
California	NRP1128
Colorado	5994
Connecticut	PCN 0002285
Delaware	1085
Florida	PH25743
Hawaii	746
Idaho	18296MS
Illinois	054017719
Indiana	64001232A
Iowa	4033
Kansas	22-02897
Kentucky	MA1537
Louisiana	PHY.006404-OS
Maine	M040001171
Maryland	PO5623
Minnesota	263770
Missouri	2011041686
Mississippi	10057 (Controlled Substance)/ 09071 (Non-Res pharmacy 7.1)
Montana	3252
Nebraska	670

State	Number
New Hampshire	NR0846
Nevada	PH02802
New Jersey	28RO00060500
New Mexico	PH00003301
New York	30775
North Dakota	678
Ohio	NTP.022149350 03
Oklahoma	99-5725
Oregon	RP-0002650-CS
Rhode Island	PHN10227
South Carolina	13323
South Dakota	400-0935
Tennessee	4974
Texas	27556
Utah	8188193-1708
Vermont	36.0078497
Virginia	0214001372
Washington	PHNR.FO.60229239
West Virginia	MO 0560316
Wisconsin	671-043
Wyoming	NR-50460

Investigator Signature: Cheryl Cathum **Date:** 5/3/12

Supervisor Signature: _____ **Date:** 5/3/12

SECTION II

COMPLAINT

Lathum, Cheryl (DPH)

From: [redacted]
Sent: Tuesday, December 13, 2011 11:55 AM
To: Lathum, Cheryl (DPH)
Subject: [redacted] COMPLAINT FORM
Attachments: hppscan1.pdf

Dear Ms. Lathum,

I have attached the signed Pharmacy Board Complaint Form. This email allows you to release the following information I attached to the complaint:

- Certificate of Analysis
- [redacted]
- Cover letter I signed dated Nov 16, 2011 along with details of complaint.

The name of the individual I spoke to at Royal Palm Florida that also claimed ownership of the pharmacy is Jordan Katz. I will forward a picture of the T3 alongside a ruler this week.

Do you have all the information you need to proceed with the complaint?

[redacted]

PHARMACY BOARD COMPLAINT FORM

DPH Date Rec'd (stamp)

DEPARTMENT OF PUBLIC HEALTH

DIVISION OF HEALTH PROFESSIONS LICENSURE
OFFICE OF PUBLIC PROTECTION
TEL (617) 973 – 0865 FAX (617) 973-0985 TTY (617) 973-0895
http://www.mass.gov/dph/boards/

DPH USE ONLY:
Entered into Database (date) 11, 28, 11 Complaint # PH4-2011-0309 Initials RH

Please complete this form as fully as possible. Please TYPE or WRITE LEGIBLY in ink.

COMPLAINANT

☐ Mr. ☐ Mrs. ☐ Ms. [redacted]

Your Last Name | Your First Name | Patient's Name (if different) | Patient's Age

Your Business Name: _____
(if applicable)

Business Address: _____ Street | City | State | Zip

Complainant Address: [redacted] Street | City | State | Zip

Patient's Address (if different): _____ Street | City | State | Zip

Your Primary Phone number: [redacted] Your Secondary Phone number: ( ) Your Email: [redacted]

LICENSEE

☑ PHARMACIST ☐ PHARMACY TECHNICIAN ☐ INTERN

Rubin | Mark and Agnes | DS89765
Licensee's Last Name | Licensee's First Name | Lic # (if known)

☑ DRUGSTORE / PHARMACY
☐ WHOLESALE DISTRIBUTOR

Phone #: 508 461-4045

Business Address: 118 Main Street | Webster | MA | 01570
Street | City | State | Zip

COMPLAINT DESCRIPTION

NATURE OF COMPLAINT:

☑ Medication error ☑ Impairment ☑ Practice beyond the scope of practice ☐ Drug diversion
☑ Patient abandonment/neglect ☐ Unlicensed practice ☐ Criminal conviction/conduct ☐ Other (specify)

DATE(S) OF INCIDENT(S): July 31, 2011 and August 1, 2011

DETAILS OF COMPLAINT: Clearly describe the incident(s) leading up to your complaint. If applicable, attach copies of documents such as prescriptions, photographs, witness statements, etc. which support your statements. DO NOT SEND ORIGINALS. Attach extra paper as needed to complete this section.

See attached

Continue on next page if needed

DESCRIPTION CONT.

Details of Complaint continued:

COMPLAINT DETAILS

Have you discussed this matter with the licensee, the licensee's office or facility ☑ yes ☐ no

If yes, name and phone number of person contacted _____

Date of contact See Cover letter How was contact made? (phone, e-mail, letter, in person) _____

Result of contact: _____

See Cover letter + Summary

Witness name(s) and telephone number(s) (if applicable) See Cover letter + Summary

Have you filed this complaint with any other state or federal agencies? No If yes, explain _____

If this complaint is against a person or entity licensed by the Pharmacy Board, are you willing to testify in person regarding this matter at a formal hearing?

☑ Yes, I am willing. ☐ No, I am not willing

AUTHORIZATION FOR RELEASE OF RECORDS AND REFERRAL OF COMPLAINT

My signature on this form, or photocopy thereof, authorizes the Department of Public Health Office of Public Protection to: (1) receive copies of all my health records relating to my complaint; (2) to share the complaint and all related attachments with the licensee; and (3) to refer my complaint to other regulatory and/or law enforcement authorities for appropriate action.

I understand that all complaints are investigated to determine their factual basis.

The act of filing a complaint and its receipt and/or investigation by DPH does not mean that disciplinary action will be taken against the licensee.

I hereby declare that I am at least 18 years old and affirm under penalties of perjury that the information provided in connection with the foregoing complaint is true and correct to the best of my knowledge, information and belief.

[redacted]

Signature of

☐ Patient or

☐ Legal Representative, or (attach documentation)

☑ Other Complainant

Dec 13, 2011

Date

Mail this form to:

Department of Public Health
DHPL Office of Public Protection
239 Causeway Street, 4th Floor
Boston, MA 02114

[redacted]

November 16, 2011

RECEIVED
NOV 17 2011
OFF. PUBLIC PROTECTION

Mr. Samuel Pente, RPh
Supervising Investigator
Department of Public Health
DHPL Office of Public Protection
239 Causeway St. 4th Floor
Boston, MA 02114

Dear Mr. Pente,

Subject: Royal Palm Specialty Pharmacy Webster, MA Overdose

I am enclosing the following for review:

- Pharmacy Board Complaint Form
- Chronological Summary of Details of Complaint
- Royal Palm Specialty Pharmacy (Webster, MA) Universal Claim Form for a Compounded Medication
- Analytical Research Laboratories Certificate of Analysis
- Medical Records

Additionally, I am providing the following information which may be beneficial to the investigation.

- A copy of a Royal Palm advertisement, dated August 3, 2011, is attached for your review. It has the names and pictures of the employees at the time of the incident. Based on information and belief, the employee's name that compounded the T3 (Liothyronine) overdose is Gina Franconeri. This individual is not listed as a Pharmacy Technician, Pharmacy Intern, or Pharmacist at the Massachusetts Division of Health Professions Licensure License Verification Site (attached). The pharmacist Karen Blakely, license number PH21868 with a Connecticut address, is listed as a "Manager of Record" for Royal Palm under Licensee Information (attached). I question whether or not any of the employees that are compounding have attended courses offered by PCCA or another qualified source that offers training.
- The fact that Royal Palm Specialty Pharmacy made an improper dispensing error associated with an overdose that caused serious injury was communicated verbally and in writing on numerous occasions. There were two phone conversations on Monday, August 1, 2011: The first was when I received a phone call from Karen Blakely, the

pharmacist at Royal Palm [redacted]. In this conversation, Ms Blakely stated she just learned they made an error compounding [redacted] prescription and that it was not 10mcg but an overdose. [redacted]

The second phone conversation [redacted] when I phoned Ms. Blakely at Royal Palm to verify the particular name of the medication and to ask the actual amount of the overdose [redacted] When asked these questions, Ms. Blakely responded by stating she was "not sure" but said repeatedly "it was a big overdose, maybe 10 mg but we really don't know". The third communication was in writing on August 15, 2011 which was regarding a request to Royal Palm to supply the name of their insurance carrier. Another communication took place by phone in August 2011 when contact was made with the insurance company notifying them that [redacted] Despite Royal Palms knowledge of their overdose error which they knew resulted in serious harm to [redacted], as of Friday, October 28, 2011 they have not complied with their "Duty to Report Certain Improper Drug Dispensing to the Board" in accordance with Massachusetts General Laws.

[redacted]

At this time, please keep the Medical Records and Certificate of Analysis in confidence.

Please perform an investigation of Royal Palm in Webster, MA. If you require additional information or have any questions please feel free to contact me at [redacted] or [redacted]

Thank you,

[redacted]

PHARMACY BOARD COMPLAINT FORM

Details of Complaint- Royal Palm Specialty Pharmacy Webster, MA

Friday, July 29, 2011

Picked up T-3 10 mcg SR capsule from Royal Palm Specialty Pharmacy located at 118 Main Street in Webster, MA 01570.

See attached Royal Palm "Universal Claim Form for a Compounded Medication", which states. This medication was labeled as described.

- Medication Name T-3 10 mcg SR capsule
- Prescription Number Rx # 213881
- Quantity Dispensed 30 caps
- Dosage Form Capsule
- Strength 10 mcg SR
- Ingredients Liothyronine Sodium, USP; Hypromellose USP; Cellulose, NF (microcrystalline)
- Signed by pharmacist Karen Blakely on 7/29/2011. Pharmacist's License # PH 21868. State ID #DS89765